PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

To:

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Date of mailing *(day/month/year)* 27 October 2005 (27.10.2005)	
Applicant's or agent's file reference GUID.632PCT	**IMPORTANT NOTICE**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2004/010917	09 April 2004 (09.04.2004)	11 April 2003 (11.04.2003)

Applicant
CARDIAC PACEMAKERS, INC.

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

HOLLINGSWORTH & FUNK, LLC
CPI Ref. No.: 03-550PCT
Date Sent: 11/10/05
Atty. Initials: MAL

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference GUID.632PCT	**FOR FURTHER ACTION** See item 4 below	
International application No. PCT/US2004/010917	International filing date *(day/month/year)* 09 April 2004 (09.04.2004)	Priority date *(day/month/year)* 11 April 2003 (11.04.2003)]
International Patent Classification (IPC) or national classification and IPC [7] A61N 1/362		
Applicant CARDIAC PACEMAKERS, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 12 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 14 October 2005 (14.10.2005)
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/US2004/010917	International filing date *(day/month/year)* 09.04.2004
Priority date *(day/month/year)* 11.04.2003	
International Patent Classification (IPC) or both national classification and IPC A61N1/362	
Applicant CARDIAC PACEMAKERS, INC.	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2004/010917

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 15-56,87-101

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 15-56,87-101

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☒ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	4-6, 9-13, 60, 65, 70, 85, 86
	No:	Claims	1,2,3,7,8,14, 57-59, 61-64, 66-69, 71-84
Inventive step (IS)	Yes:	Claims	4-6,9-12
	No:	Claims	1, 2, 3, 7, 8, 13, 14, 57-86
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III.

Claims 15-28 relate to subject-matter considered by this Authority to be covered by the provisions of **Rule 67.1(iv) PCT**, because their subject-matter relates to a method for treatment of the human body by therapy, since modifying the delivery of the anti-arrhythmia therapy implies that the patient will benefit from this modification and some suffering of the patient will be alleviated.
Claims 29-56 relate to subject-matter considered by this Authority to be covered by the provisions of **Rule 67.1(iv) PCT**, because their subject-matter relates to a method for treatment of the human body by therapy, since withholding unnecessary anti-arrhythmia treatment prevents a feeling of pain or discomfort, and since "withholding delivery if the sensed signal is not the cardiac signal" implies implicitly also delivering a therapy if the sensed signal is the cardiac signal.
Claims 87-101 relate to subject-matter considered by this Authority to be covered by the provisions of **Rule 67.1(iv) PCT**, because their subject-matter relates to a diagnostic method practised on the human or animal body.

Re Item IV.

1 The separate inventions/groups of inventions are:

Claims 1-14:
An ICD with one or more electrodes, which are capable of developing a cardiac activity signal and a patient activity signal.

Claims 57-86:
An ICD with an additional non-electrophysiologic sensor that verifies the quality of the detected ECG signal.

2 They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

2.1 Document:US-A-6 144 879 (D8) is considered to be the prior art.

D8 discloses the common features of claims 1-14, 57-86, which is: (the references in parenthesis referring to D8):
an implantable device, comprising:

- an implantable housing (see fig. 8);
- an electrode arrangement (15) configured for subcutaneous non-intrathoracic placement (see column 4, lines 28-27) *(epicardial electrodes are suitable (configured) for subcutaneous non-intrathoracic placement)*, the electrode arrangement sensitive to cardiac activity;
- means for sensing a second signal (see column 11, lines 63-67);
- detection circuitry provided in the housing, coupled to the electrode arrangement (see column 12, lines 17-22);
- energy delivery circuitry, coupled to the electrode arrangement (see column 12, lines 17-22);
- a processor (170) provided in the housing and coupled to the energy delivery and detection circuitry, the processor using both the cardiac activity signal and the second signal (see column 12, lines 23-44)).

Hence, the common features of claims 1-14,57-86 are known.

2.2 The difference between the subject-matter of claims 1-14,57-86 and D8 is the contribution which those claims make over the prior art D8 and is regarded as the special technical feature (STF) of those claims in the sense of Rule 13.2 PCT.

Three possible special technical features in the sense of Rule 13.2 PCT can be identified in the claims 1-14,57-86:

- STF 1 (claims 1-14): the patient activity signal is developed from a signal measured with the *same* electrodes that sense the cardiac activity (D8 discloses already that the second signal is indicative of the activity state of the patient, and uses it for modifying the therapy, see column 12, lines 1-44);
- STF 2 (claims 57-62): the processor *verifies the sensed ECG using the additional signal* in order to decide to withhold the treatment or not;
- STF 3 (claims 63-86): the additional signal is a blood sensor signal; the processor *verifies the sensed ECG using the blood sensor signal* in order to evaluate a cardiac rhythm.

The above mentioned three STFs are not only different, they are also not corresponding because they relate to different two objective problems to be solved, namely:
- STF 1: how to sense a patient activity state without using an additional sensor
- STFs 2,3: providing an alternative use of an additional sensor

2.3 Therefore, no technical relationship involving one or more of the same or corresponding STFs in the sense of Rule 13.2 PCT exists among the subject-matter of claims 1-14, 57-86.

Hence, the requirement of unity according to Rule 13.1 PCT is not fulfilled.

Re Item V.

1 The following documents are referred to in this communication:

D1 : US 2002/107552 A1 (GILKERSON JAMES O ET AL) 8 August 2002 (2002-08-08)

D2 : US 2002/147474 A1 (MORRIS MILTON ET AL) 10 October 2002 (2002-10-10)

D3 : US 5 417 714 A1 (LEVINE PAUL ET AL) 23 May 1995 (1995-05-23)

D4: EP-A-0 488 512 (TELECTRONICS NV) 3 June 1992 (1992-06-03)

D5: WO 03/020367 A (MEDTRONIC INC) 13 March 2003 (2003-03-13)

D6: US-A-6 122 536 (SUN XIAOGUONG ET AL) 19 September 2000 (2000-09-19)

D7: US-A-5 556 421 (PRUTCHI DAVID ET AL) 17 September 1996 (1996-09-17)

D8: US-A-6 144 879 (GRAY NOEL DESMOND) 7 November 2000 (2000-11-07)

2 CLAIMS 1-14

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 1** is not new in the sense of **Article 33(2) PCT**.

Document D1 discloses all the features of claim 1 (the references in parenthesis applying to this document):
an implantable cardiac stimulation device, comprising:

- a housing configured for subcutaneous non-intrathoracic placement in a patient (par. 28);
- energy delivery circuitry provided in the housing (fig. 2, 106);
- detection circuitry provided in the housing (fig. 2, 104);
- one or more electrodes coupled to the energy delivery and detection circuitry and configured for subcutaneous non-intrathoracic placement in a patient (fig. 1 and par. 22: patch electrodes are suitable (configured) for subcutaneous non-intrathoracic placement), the one or more electrodes sensitive to cardiac and muscle activity *(the electrodes of D1 are sensitive to the heart, but the heart is also a muscle)*; and
- a processor (fig. 2, 100) provided in the housing and coupled to the energy delivery and detection circuitry, the processor detecting an arrhythmia using a cardiac signal developed from the sensed cardiac activity (par. 6) and detecting an activity state of the patient using an activity signal developed from the sensed muscle activity (par. 52), the processor modifying delivery of a therapy that treats the arrhythmia in response to the activity signal (par. 68).

2.2 For the sake of completeness, it is pointed out that also the teaching of document D2 (paragraphs 33, 39-42) is novelty-destroying (Article 33(2) PCT) for the subject-matter of claim 1.

2.3 Dependent claims 2, 3, 6, 7, 8, 13, 14

Dependent **claims 2, 3, 6, 7, 8, 13, 14** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (**Article 33(2) and (3) PCT**), see the following passages:

- **claim 2**: D1, paragraphs 63, 67, 58
- **claim 3**: D1, paragraph 52
- **claim 6**: D3, column 14, line 49 - column 15, line 15
- **claim 7**: D1, paragraph 51
- **claim 8**: D1, paragraphs 30 and 63: cardiac signal (VT-1,VT,VF) is developed from the heart rate of the electrocardiogram, activity signal from the heart range change of the electrocardiogram
- **claim 13**: obvious design option: dual-chamber sensing with blanking and refractory periods is commonly used in ICDs nowadays.
- **claim 14**: D1, paragraph 6.

2.4 Dependent claims 4-5, 9-12

The subject-matter of **claims 4-5, 9-12** would appear to be novel and inventive in view of the known state of the art (Article 33(2), 33(3) PCT).

- claims 4,5: D1 discloses a maximum inhibition time, after which the therapy is delivered - even if the activity signal is not yet present anymore (see paragraphs 53,54,68). All the available prior art that inhibits a therapy after an increase in activity, shows that the inhibition only lasts as long as the activity is increased.

- claims 9,10: In D1, the activity state of the patient is calculated if the heart rate increases rapidly. Hence the "muscle" is in fact the cardiac muscle. Although the cardiac and activity signals are detected by the same means (the cardiac electrodes), they come from the same source (the heart), and therefore they need not be separated.
D4 uses a separate activity sensor (e.g. accelerometer). In other words, although here the source is different, also the detecting means for the cardiac and the activity signal is different, so there is no question of signal separation.
So the available prior art does not teach the need of separation of such signals.

3 CLAIMS 57-62

3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 57** is not new in the sense of **Article 33(2) PCT**.

Document D4 discloses all the features of claim 57 (the references in parenthesis applying to this document) (see fig. 2):
An implantable cardiac device (7), comprising:
- an implantable housing;
- an electrode arrangement (10) configured for subcutaneous non-intrathoracic placement;
- detection circuitry (18, 19) provided in the housing and coupled to the electrode arrangement, the detection circuitry configured to detect electrocardiogram signals;
- a sensor (15a) configured to sense signals associated with a non-electrophysiological cardiac source;

- energy delivery circuitry (21, 22, 23) coupled to the electrode arrangement; and
- a processor (20) provided in the housing and coupled to the detection circuitry, sensor, and energy delivery circuitry, the processor using the non-electrophysiological signals to verify that the detected electrocardiogram signals comprise a cardiac signal, the processor withholding treatment of the cardiac arrhythmia if the detected electrocardiogram signals do not comprise the cardiac signal *(see p. 6, lines 32-35: only initiating therapy in case of both a high rate (detected with ECG) and a haemodynamically compromising situation (detected with pressure sensor); no detection of a haemodynamically situation indicates ECG-sensing failure such as breakage of conductor or noise (see p. 1, lines 10-25), i.e. detected ECG does not comprise a cardiac signal).*

3.2 For the sake of completeness, it is pointed out that also the teaching of documents D5 (see fig. 9) and D6 (see column 16, lines 16-35 and column 18, lines 40-68) take away the novelty of the subject-matter of claim 57 (Article 33(2) PCT).

3.3 Dependent **claims 58-62** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (**Article 33(2) and 33(3)**), for the following reasons:

Document D4 discloses all the features of
- **claims 58, 5**9: see fig. 3 (21, 22, 23)
- **claim 61**: see fig. 3 (15)

Document D5 discloses all the features of
- **claim 62**: see p. 3, lines 17-18

The features of **claim 60** are a normal design option for the skilled person, see e.g. D7, abstract and fig. 3.

4 CLAIMS 63-86

4.1 Documents D4 (see p. 6, lines 12-48), D5 (see fig. 9 and p. 22, lines 9-17) and D6 (see column 16, lines 16-35 and column 18, lines 40-68) disclose all the features of claim 63. Hence **claim 63** does not meet the requirements of **Article 33(2) PCT**.

4.2 Dependent **claims 64-86** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (**Article 33(2) and 33(3)**), for the following reasons:

Document D6 discloses all the features of
- **claim 64**: see column 19, lines 26-29
- **claims 66-69, 71-72**: see column 5, lines 37-50; column 15, lines 44-52; column 20, lines 1-2
- **claim 84**: see column 5, line 59

Document D4 discloses all the features of
- **claims 73, 74**: see fig. 3 and p. 7, lines 6-17
- **claims 75-79, 81**: see p. 6, lines 46-47 and p. 7, lines 15-20
- **claim 80**: see abstract
- **claim 82**: see p. 5, lines 14-16
- **claim 83**: see fig. 1

The features of **claim 65** (see e.g. D7, abstract and fig. 3), **claim 70** and **claims 85, 86** are normal design options for the skilled person.